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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/951,832	10/16/1997	CESAR Z. LINA	VAC.312B.US	2039

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LEGAL DEPARTMENT INTELLECTUAL PROPERTY  
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EXAMINER
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HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

NIT

<b>Office Action Summary</b>	<b>Application No.</b> 08/951,832	<b>Applicant(s)</b> LINA ET AL.	
	<b>Examiner</b> Melanie J. Hand	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-8, 13, 16-25 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) 13, 16-21 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-8, 22-25, 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments, see Remarks, page 9, filed November 8, 2006, with respect to the rejection(s) of claim(s) 8 under 35 U.S.C. 103, specifically the limitation of a pressure sensitive adhesive in claim 8, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

Applicant's arguments, pages 8 and 10, filed November 8, 2006 with respect to the remainder of the limitations of claim 8 and its dependent claims have been fully considered but they are not persuasive. With respect to applicant's arguments regarding the rejection of the claims under 35 U.S.C. 103(a) over Todd in view of Martin: Applicant argues that the backing of Todd does not secure the porous pad within a sealable space defined in part by a wound surface. Examiner refers applicant to Col. 2, lines 54-63, wherein Todd clearly teaches that the pad of the instant invention is intended for use at a surgical site where interstitial fluid is present, i.e. a sealable space defined at least in part by a wound surface. The fact that the foam pad is placed against the area merely indicates that pressure is put upon the wound surface by the pad and is not evidence of absence of a sealable space. In response to applicant's argument that the pad backing is intended to provide flexible support and not secure the pad in anything, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Further, Examiner refers applicant to Col. 4, lines 57-66, wherein Todd teaches that "[b]acking plate 16 is preferably constructed of a flexible and pliable material which

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can be bent and manipulated. This allows foam pad 12, attached to flexible backing plate 16, to be folded into various configurations to fit into various areas of the body with the absorbent portion facing outward." This is clearly a teaching by Todd that the elastomeric backing is at least capable of, if not directly responsible for, securing said porous pad in a sealable space.

With respect to applicant's arguments regarding the prior art of Martin: As requested, Examiner has added citations in this Office action where Martin explicitly teaches that motivation to combine the device of the instant invention with the prior art device of Todd.

#### ***Election/Restrictions***

Newly submitted claims 28-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 28 sets forth a means for preventing fluids from contaminating the means for collecting fluids. Such means for preventing is defined in Page 20, lines 3-7 of the Specification and comprises a control system that is a feature of the non-elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3, 4, 8, 22, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd et al (U.S. Patent No. 5,437,651) in view of Martin (U.S. Patent No. 4,631,061) and further in view of Seymour (U.S. Patent No. 4,460,369).

With respect to **claim 8**: Todd teaches a medical suction apparatus comprising an open celled polyurethane foam pad (porous pad permeable to fluids) that is foldable so as to be capable of being placed in various areas of the body between tissues (e.g. a sealable space defined in part by a wound surface). ('651, Col. 4, lines 37-39, 63-65) Tubing 20 connecting pad 12 to a suction source has a first end threaded through orifice 18 of pad backing 16 that is in fluid communication with pad 12 (Figs. 5,6). A receptacle (not shown) is attached to the apparatus 10 to collect fluid from the body through said tubing 20. Foam pad 12 with backing 16 is attachable to a suction source 14 via tubing 20 therefore the second end of tubing 20 is attached to the suction source, which in turn is operatively attached to said receptacle. Therefore said receptacle is in fluid communication with a second end of tubing 20 that is opposite the first end. Todd teaches that the apparatus is adaptable to receive a pump as a means for supplying intermittent suction to the apparatus connected thereto and operated manually or automatically for periodic drainage. ('651, Col. 7, lines 26-30) Since the pump is a suction source, it is thus fluidically connected to said receptacle.

Todd does not teach at least one bacterial filter interposed between said receptacle and said pump. Martin teaches a portable urine collection and storage device comprising a collection vessel 22 for collecting urine from a user's body, a tube 24 connecting said receptacle to a urine tank 32 and a filter 50 disposed between said tank and pump 43. ('061, Col. 2, lines 65-68, Col. 3, lines 1-6, 65-68) Martin teaches that filter 50 prevents urine odor from escaping to the atmosphere (see Abstract). Since bacteria are larger than substantially all molecules of

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compounds which cause odor, filter 50 is fully capable of functioning as a bacterial filter. Martin teaches that the filter in this position has the dual function of preventing urine odor from escaping said urine tank and reducing pump noise ('061, Col. 3, line 65 – Col. 4, line 1), therefore it would be obvious to one of ordinary skill in the art to modify the device taught by Todd so as to contain a bacterial filter between said receptacle and said suction source to which it is fluidically connected so as to prevent odor and bacteria from escaping from or entering the receptacle as taught by Martin.

Neither Todd nor Martin teaches at least peripheral areas with pressure-sensitive adhesive. Seymour teaches a sheet material coated with adhesive that is suitable for use as a surgical drape to be placed over a wound dressing. Seymour teaches that placing the sheet flat over the wound (thus defining areas of pressure sensitive adhesive extending beyond the periphery of said dressing) facilitates the retention of that wound exudates which is protective and healing ('369, Col. 2, lines 6-8), therefore it would be obvious to one of ordinary skill in the art to modify the combination taught by Todd and Martin by applying the drape taught by Seymour so as to provide peripheral areas with pressure-sensitive adhesive that extend beyond the periphery of the pad taught by Todd and Martin so as to retain healing wound exudates.

With respect to **claim 3**: Todd teaches that the receptacle is fluidically connected to said pump, said receptacle is attached to the housing for said suction source ('651, Col. 4, lines 46-48) and is thus also removably attached.

With respect to **claim 4**: Todd does not teach that said receptacle is removably received in a recess in the housing of said pump. Martin teaches housing 20 that encloses pump 43 and urine tank 32, which defines a space (recess) having a volume. Since they are connected via tubing

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only, urine tank 32 is removably received in housing 20 and is thus also removably received in the recess it occupies.

With respect to **claims 22,23**: Todd teaches an open-celled polyurethane foam, i.e. having at least 95% interconnecting cells forming a network (reticulated), wherein polyurethane is produced from a polyol (polyether) and a diisocyanate.

With respect to **claim 27**: Neither Todd nor Martin teaches peripheral areas with pressure-sensitive adhesive extending beyond the periphery for adhering to intact skin around the wound. Seymour teaches a sheet material coated with adhesive that is suitable for use as a surgical drape to be placed over a wound dressing. Seymour teaches that placing the sheet flat over the wound (thus defining areas of pressure sensitive adhesive extending beyond the periphery of said dressing) facilitates the retention of that wound exudates which is protective and healing ('369, Col. 2, lines 6-8), therefore it would be obvious to one of ordinary skill in the art to modify the combination taught by Todd and Martin by applying the drape taught by Seymour so as to provide peripheral areas with pressure-sensitive adhesive that extend beyond the periphery of the pad taught by Todd and Martin so as to retain healing wound exudates.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd et al ('651) in view of Martin ('061) and further in view of Seymour (U.S. Patent No. 4,460,369) as applied to claims 3,4,8,22, 23 and 27 above, and further in view of Poirier et al (U.S. Patent No. 4,886,502).

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With respect to **claim 5**: Neither Todd nor Martin nor Seymour teaches tubing fitted as an interference fit with said orifice into an interior portion of said pad. Poirier teaches a peritoneal access device comprising a porous polyurethane filament (polymer foam having interconnecting cells ('502, Col. 4, lines 14-18)) peritoneal collar 84 into which the peritoneum 87 and adjacent tissue can grow. Collar 84 is positioned by sliding said collar onto tube 82 wherein the inner diameter of collar 84 is smaller than the outer diameter of tube 82 so as to form an interference fit. Poirier teaches that this interference fit provides a stable seal as well as sufficient friction to prevent the collar from moving once it is properly positioned by a surgeon ('502, Col. 4, lines 5-35), therefore it would be obvious to one of ordinary skill in the art to modify the pad orifice taught by the combined teaching of Todd and Martin and Seymour so as to have an inner diameter that is smaller than the outer diameter of tubing 20 as taught by Poirier to form an effective seal and secure said pad at the desired wound site.

With respect to **claim 7**: Todd teaches an open-celled polyurethane foam, i.e. having at least 95% interconnecting cells forming a network (reticulated), wherein polyurethane is produced from a polyol (polyether) and a diisocyanate.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand  
Examiner  
Art Unit 3761

January 17, 2007

**TATYANA ZALUKAEVA**  
**SUPERVISORY PRIMARY EXAMINER**

